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Section D: 510(k) Summary

JAN - 4 2008

Inspiration® Ventilator System

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

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Date Prepared: September 13, 2007

Device Trade Name: Inspiration® Ventilator System

Common Name: Continuous Ventilator

Device Class: Class II
per 21 CFR 868.5895

Product Code: 73 CBK

Predicate Device: The predicate devices are:

Manufacturer/Product	510(k)	Classification
eVent Medical, Inc. Inspiration® Ventilator System (technological equivalence)	K051550	Class II, Continuous Ventilator Per 21 CFR 868.5895
VIASYS Respiratory Care, Inc. AVEA Ventilator (Heliox use equivalence)	K062093	Class II, Continuous Ventilator Per 21 CFR 868.5895



Device Description:

The Inspiration Ventilator System provides continuous ventilation to infant, pediatric and adult patients requiring respiratory support by means of pressure-based and volume-based mandatory and spontaneous breaths. The device is identical to the cleared device, the Inspiration Ventilator System, with the addition of the capability to deliver a Heliox gas mixture.

This modification is implemented on the Inspiration Ventilator through additional functionality in hardware and software. The existing modalities, pneumatic design, electrical circuitry and user interface mechanism have remained unchanged from the cleared Inspiration Ventilator device.

Intended Use:

The device intended use is the same as that of the cleared device, the Inspiration Ventilator system and is re-stated below.

Purpose and Function of the Device:

The Inspiration Ventilator System is intended to provide continuous ventilation for patients requiring respiratory support. This product is intended for a wide range of patients from infant to adult and for a wide variety of clinical conditions.

Intended Patient Population:

The intended patient population includes infant through adult patients who require pressure-based or volume-based continuous respiratory support with tidal volumes as low as 5 ml and inspiratory pressures as low as 1 cm H₂O.

Intended Environment of Use:

The device is intended for use in hospitals and hospital-type facilities, which provide respiratory care for patients requiring respiratory support.

The device may be used for intra-hospital transport within a hospital or hospital-type facility. The device is not intended for transport between hospitals or hospital-type facilities.

The device is not to be used in the presence of flammable anesthetics.

The device is intended for sale by or on the order of a physician only. The device is intended for operation by trained and qualified personnel

Indication for Use:

The Inspiration Ventilator System is indicated for use with a wide range of patients from infant through adult, requiring respiratory support for a wide range of clinical conditions in hospital, hospital-type facilities and intra-hospital transport.



Substantial Equivalence:

The intended use of the Inspiration Ventilator is the same as that for standard, currently marketed critical care ventilators. The materials and design of this device are similar to those of the predicate devices. The technical characteristics of the Inspiration Ventilator System do not introduce new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with the Inspiration Ventilator System provides similar information as the predicate devices.

Information provided in the 510(k) submission supports the determination of substantial equivalence to deliver a Heliox/Oxygen gas mixture. Software design and development, (including verification and validation testing, test and software quality procedures) was conducted using FDA's Guidance for the Content of Premarket Submissions for Software contained in medical devices, dated May 11 2005, as guidance and per internal company procedures. The Inspiration Ventilator device design and testing are also compliant with 21 CFR 820.30 Design Control and various voluntary, international standards identified in the Cover Letter.

Conclusion:

The Inspiration is a Heliox friendly ventilator that operates the same with Heliox as it does with compressed air and 100% O₂. A review of the clinical literature on the operation of the Inspiration with Heliox is consistent with eVent Medical's bench studies of the Inspiration with high percentages of Helium.

The Inspiration is safe in that it is impossible to deliver an anoxic mixture of gas. FIO₂ delivery is precisely accurate to FIO₂ set.

All literature reviewed agrees that Heliox poses no increased health risk when used as a carrier gas in mechanical ventilators.

In summary, eVent Medical has demonstrated the Inspiration Ventilator System to be safe and effective. This device is equivalent to its predecessor and substantially equivalent to currently marketed devices which have been previously cleared by FDA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN - 4 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Lundberg
Vice President, Regulatory Affairs and Quality Assurance
eVent Medical, Incorporated
81 Columbia, Suite 101
Aliso Viejo, California 92656

Re: K072590

Trade/Device Name: Inspiration® Ventilator System
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: December 20, 2007
Received: December 26, 2007

Dear Mr. Lundberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chi Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Section B: Indications for Use Statement

510(k) Number:

K072590

Device Name:

Inspiration® Ventilator System

Indications for Use: The Inspiration® Ventilator is indicated for use with a wide range of patients from infant through adult, requiring respiratory support for a wide range of clinical conditions in hospital, hospital-type facilities and intra-hospital transport.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

J. C. C.
(Division Sign-Off) acting
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072590